K013825

CANDELA

FEB 1 5 2002

General Information: This 510(k) is to provide notification of substantial equivalence for the Candela Smoothbeam Laser System, which is substantially equivalent to a previously marketed device intended for use in the treatment of periorbital wrinkles.

Submitted by:	Candela Corporation
Address:	530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Nelson Manager, Regulatory Affairs
Date Prepared:	November 16, 2001
Device Trade Name:	Smoothbeam Laser System
Device Common Name:	Dermatology Laser
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Predicate Devices:	Laser Aesthetics CoolTouch (K003715) and Candela 1450 nm Diode laser (K002421)

Description of the Smoothbeam Laser System: The Diode laser is a Continuous Wave, diode medical laser, controlled by an embedded processor, for use in dermatology for the treatment of periorbital wrinkles. The Candela Smoothbeam Laser System is comprised of a power supply, optical delivery system, software control system and Dynamic Cooling Device. The laser output energy is delivered via an optical fiber to a handpiece, which produces circular beams on the skin. The Dynamic Cooling Device provides a short burst of cryogen spray during the laser treatment. The cryogen is delivered via a hose to a nozzle located in the handpiece. The Dynamic Cooling Device functions to cool the skin during the laser treatment minimizing thermal damage to skin during laser treatment and reducing pain associated with laser treatment. The Candela Smoothbeam Laser System is equipped with safety interlock systems to protect patients and operators. Users of the device, make selections from a control panel to regulate operation during the laser treatment.

Intended use of Smoothbeam Laser System: The Smoothbeam Laser System is indicated for the treatment of periorbital wrinkles.

Performance Standards: As a laser product, the Smoothbeam Laser System is required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition, the device will conform to the UL 2601 Electrical Safety Standard and with the Harmonized Standard EN 60601-1-2, Part 2 established by the European Community.

Clinical Performance Data: Clinical trials produced results that indicate that the Smoothbeam Laser System is effective in the treatment of periorbital wrinkles.

Summary of Substantial Equivalence: The Candela Smoothbeam Laser System has the same intended use, utilizes similar operating principles and matches key design aspects, including spot size, similar wavelength and/or the same maximum delivered power as the predicate device. On the basis of similarities in methods of assembly, method of operation, and intended uses, Candela believes that its Smoothbeam Laser System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2002

Ms. Lorraine Nelson
Manger, Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, MA 01778

Re: K013825
Trade/Device Name: Candela Smoothbeam Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 16, 2001
Received: November 19, 2001

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CANDELA

INDICATION FOR USE STATEMENT

510(k) Number (if known): K 013825

Device Name: Candela Corporation Smoothbeam Laser System

Indications For Use:

The Candela Smoothbeam Laser System is indicated for Use in dermatology for incision, excision, ablation, vaporization with hemostasis of soft tissue and the treatment of periorbital wrinkles.

The intended use of the Candela Dynamic Cooling Device is:
Cooling of the skin prior to laser treatment
Reduction of pain during laser treatment

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
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510(k) Number K013825